

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESAL PRICE  
LITIGATION

MDL No. 1456

C.A. No.: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO  
ALL CLASS ACTIONS

Judge Patti B. Saris

**WATSON PHARMACEUTICALS, INC.'S RESPONSE TO CLASS  
PLAINTIFFS' RESPONSE TO AMGEN AND WATSON'S  
SUPPLEMENTAL OPPOSITION TO CLASS CERTIFICATION**

Exhibit 2: Medicare Dialysis Facilities: Beneficiary Access  
Stable and Problems in Payment System Being  
Addressed, GAO-04-450 (June 2004).

United States General Accounting Office

GAO

Report to Congressional Committees

June 2004

# MEDICARE DIALYSIS FACILITIES

## Beneficiary Access Stable and Problems in Payment System Being Addressed



GAO-04-450

June 2004



Highlights of GAO-04-450, a report to congressional committees

## MEDICARE DIALYSIS FACILITIES

### Beneficiary Access Stable and Problems in Payment System Being Addressed

#### Why GAO Did This Study

Medicare covers about 90 percent of patients with end-stage renal disease (ESRD), the permanent loss of kidney function. Most ESRD patients receive regular hemodialysis treatments, a process that removes toxins from the blood, at a dialysis facility. A small percentage dialyze at home. From 1991 through 2001, the ESRD patient population more than doubled, from about 201,000 to 406,000. As the need for services grows, so do concerns about beneficiary access to and Medicare payment for dialysis services. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 directed GAO to study beneficiaries' access to dialysis services. In this report, GAO (1) assessed the supply of dialysis facilities and the services they provide, overall and relative to beneficiary residence, and (2) assessed the extent to which Medicare payments for dialysis services are adequate and the methodology is appropriate.

In order to assess the supply of dialysis facilities, GAO used Facility Surveys collected by the Centers for Medicare & Medicaid Services (CMS) and outpatient claims, the bills submitted to Medicare by providers of certain outpatient services from 1998 through 2001. To assess the adequacy of Medicare payment and the appropriateness of the payment methodology, GAO used 2001 Medicare cost reports and outpatient claims submitted by freestanding dialysis facilities.

[www.gao.gov/cgi-bin/getrpt?GAO-04-450](http://www.gao.gov/cgi-bin/getrpt?GAO-04-450).

To view the full product, including the scope and methodology, click on the link above. For more information, contact A. Bruce Steinwald at (202) 512-7119.

#### What GAO Found

GAO found that from December 31, 1998, through December 31, 2001, the total number of dialysis facilities nationwide increased at about the same rate as the Medicare dialysis population, 16 and 15 percent, respectively, and the total number of stations (that is, treatment areas and equipment, including dialysis machines, needed to dialyze the patient) increased by over 24 percent, a rate greater than the growth in the Medicare dialysis population. The dialysis industry opened facilities in more counties across the country, although facilities were more likely to be available to beneficiaries in urban counties than in rural counties. In addition, while almost all facilities provided in-facility hemodialysis, fewer facilities provided home dialysis.

GAO estimates that total payments to freestanding dialysis facilities exceeded providers' allowable costs by 3 percent in 2001. Although payments were higher than costs overall, payments did not meet costs for small facilities. In addition, composite rate payments, intended to cover the costs of dialysis services associated with a treatment, including nursing, supplies, social services, and certain laboratory tests, were 11 percent less than the costs of providing those services, while payments for separately billed drugs, drugs not included in the composite rate, exceeded the costs of those services by 16 percent. Because of this imbalance, providers have an incentive to maximize the use of profitable separately billed drugs to compensate for inadequate payments under the composite rate.

CMS generally agreed with GAO's findings. The agency noted that it has been working to redesign the payment system since 2000. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Secretary of Health and Human Services is required to develop a report by October 1, 2005 detailing the elements and features necessary in the design and implementation of a broader payment system that includes separately billed drugs. MMA also requires the Secretary to conduct a 3-year demonstration project, beginning January 1, 2006, that uses a broader payment system incorporating patient characteristics identified in the report.

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**Abbreviations**

AAKP	American Association of Kidney Patients
AWP	average wholesale price
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CMS	Centers for Medicare & Medicaid Services
DCI	Dialysis Clinic, Inc.
EPO	epoetin
ESRD	end-stage renal disease
FMC	Fresenius Medical Care
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NIH	National Institutes of Health
NRAA	National Renal Administrators Association
PD	peritoneal dialysis
RLC	Renal Leadership Council
RPA	Renal Physicians Association

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United States General Accounting Office  
Washington, DC 20548

June 25, 2004

#### Congressional Committees

Medicare covers approximately 90 percent of all individuals who have end-stage renal disease (ESRD), the permanent loss of kidney function, and treatment of the disease results in substantial costs to the Medicare program. In 2001, Medicare spent an average of approximately \$46,600 on services for each beneficiary with ESRD, while the average per-beneficiary spending across the entire Medicare population was about \$6,200. ESRD-related expenditures have increased rapidly and are expected to continue to increase. From 1991 through 2001, the number of individuals with ESRD more than doubled, increasing from about 201,000 to 406,000. During the same time, while total Medicare expenditures increased by 108 percent, ESRD program expenditures increased by 166 percent, to almost \$15.4 billion in 2001. The ESRD population is projected to reach approximately 650,000 by 2010.<sup>1</sup>

Although some receive kidney transplants, most individuals with ESRD depend on regular treatments of dialysis, a process in which excess fluids and wastes are removed from the blood.<sup>2</sup> In 2001, about 90 percent of all dialysis patients underwent hemodialysis, typically three times per week, at one of almost 4,000 outpatient renal dialysis facilities nationwide.<sup>3</sup> In that same year, less than 1 percent of hemodialysis patients dialyzed at home, and nearly all peritoneal dialysis (PD) patients dialyzed at home.<sup>4</sup> Nationwide, about 200 hemodialysis patients dialyze five to seven times per week, known as daily hemodialysis, which is thought by some clinicians to improve patient outcomes.

<sup>1</sup>See J.L. Xue, et al., "Forecast of the Number of Patients with End-Stage Renal Disease in the United States to the Year 2010," *Journal of the American Society of Nephrology*, vol. 12 (2001): 2753-2758.

<sup>2</sup>Dialysis is administered either by a machine that filters blood through an artificial kidney (hemodialysis) or by filtering the blood through the lining of the patient's abdominal area, called the peritoneal membrane (peritoneal dialysis).

<sup>3</sup>In this report, we refer to outpatient renal dialysis facilities as "dialysis facilities."

<sup>4</sup>In this report, we use the term "hemodialysis" to refer to in-facility hemodialysis, and we use the term "home dialysis" to include both PD and home hemodialysis.

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Dialysis facilities furnish services to patients through one of two methods: they provide hemodialysis and supplies and other support services in the facility, or they provide equipment, supplies, and support services to beneficiaries who dialyze at home. Regardless of whether a beneficiary dialyzes at home or in a facility, Medicare pays the facility a fixed, prospectively determined amount per treatment, known as the composite rate, generally for up to three dialysis treatments per week. The composite rate covers many commonly used services and items; certain other items, including some drugs and supplies, are paid for separately. Medicare adjusts the composite rate to account for variation in area wages; however, there is no adjustment for length of treatment, treatment method, or beneficiary condition. By paying facilities a fixed amount, Medicare seeks to encourage them to operate efficiently, as facilities retain the difference if their payments exceed their costs of providing necessary services.

The composite rate has not been regularly updated, and is less than \$4 higher today than when it was implemented in 1983. Despite the lack of a regular update, the dialysis industry has remained profitable over the years by increasing productivity and efficiency. In recent reports, the Medicare Payment Advisory Commission (MedPAC)<sup>6</sup> has found that overall facility profits have steadily declined even though Medicare payments for separately billed drugs have exceeded facility costs. MedPAC has also found that the composite rate is covering progressively less of the costs of composite rate services.<sup>6</sup> Representatives of the dialysis industry have stated that Medicare payments are inadequate overall, and that these low payments are resulting in facility closures in certain geographic areas and may eventually lead to decreased access for beneficiaries nationwide. In 2000, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required the Secretary of the Department of Health and Human Services (HHS) to develop a payment system that includes clinical laboratory tests and drugs that are routinely used but billed separately.<sup>7</sup> With the enactment of the Medicare Prescription Drug,

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<sup>6</sup>MedPAC is an independent federal body, established by the Balanced Budget Act of 1997, that advises the Congress on issues affecting the Medicare program. See Pub. L. No. 105-33, § 4022, 111 Stat. 251, 350.

<sup>6</sup>Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington D.C.: March 2001, March 2002, and March 2003).

<sup>7</sup>Pub. L. No. 106-554, App. F, § 422(c)(1), 114 Stat. 2763, 2763A-517.



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Improvement, and Modernization Act of 2003 (MMA), the Secretary of HHS was required to continue development of a broader payment system.<sup>8</sup>

BIPA directed us to examine Medicare beneficiaries' access to dialysis services.<sup>9</sup> As agreed with the committees of jurisdiction, we (1) assessed the supply of dialysis facilities and the services they provide, both overall and relative to beneficiary residence; (2) assessed the extent to which Medicare payments for dialysis services are adequate and the payment methodology is appropriate; and (3) reviewed whether increased use of daily hemodialysis can improve patient care.

In order to measure the supply of dialysis facilities, we used the 1998 through 2002 Facility Survey files, which include information on the number of hemodialysis stations and the services provided at each facility.<sup>10</sup> These surveys are administered to all dialysis facilities, hospital-based and freestanding, by the Centers for Medicare & Medicaid Services (CMS), the agency responsible for managing Medicare.<sup>11</sup> To identify beneficiaries on dialysis and their residence, we analyzed the 1998 through 2001 Medicare outpatient claims, the bills submitted by providers of certain outpatient services to receive Medicare payment. These claims were the most recent data available at the time of our analysis. We assessed the reliability of the facility survey and claims data and found them suitable for our purposes.

To assess the adequacy of Medicare payment and the appropriateness of the payment methodology, we analyzed Medicare freestanding dialysis facility cost reports from 1998 through 2001 and Medicare outpatient claims data from 2000 and 2001. We performed this analysis in aggregate for all freestanding facilities and for different sizes of facilities, with size defined using the total number of treatments provided at a facility. The Medicare payment methodology is the same for freestanding and hospital-based dialysis facilities, but we did not analyze cost reports or claims for

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<sup>8</sup>See Pub. L. No. 108-173, § 623, 117 Stat. 2066, 2312-17.

<sup>9</sup>Pub. L. No. 106-554, App. F, § 422(d), 114 Stat. 2763, 2763A-517.

<sup>10</sup>A station is typically defined as the treatment area and equipment, including the dialysis machine, needed to dialyze the patient.

<sup>11</sup>In July 2001, the agency's name was changed from the Health Care Financing Administration (HCFA) to CMS. In this report, we refer to the agency as HCFA when discussing actions it took or was required to take under that name.

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hospital-based facilities because their reported costs are affected by decisions in allocating costs between the hospital and the dialysis facility. In 2001, about 84 percent of all dialysis facilities nationwide were freestanding. We assessed the reliability of the cost report and claims data. We excluded cost reports that had questionable data or that did not cover at least 300 days. We found the remaining cost reports and the claims data suitable for our purposes. We interviewed patient advocate organizations, clinicians, manufacturers of dialysis equipment, and representatives of the dialysis industry, and made site visits to three dialysis facilities.

In order to review daily hemodialysis, we surveyed the relevant scientific literature, interviewed physicians who provide daily hemodialysis, and visited a dialysis facility providing daily hemodialysis. Appendix I contains a more complete description of our methodology. We conducted our work from July 2002 through June 2004 in accordance with generally accepted government auditing standards.

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## Results in Brief

From December 31, 1998, through December 31, 2001, the total number of dialysis facilities nationwide increased at about the same rate as the Medicare dialysis population, 16 and 15 percent, respectively. Over the same period, the total number of stations increased by over 24 percent, a rate greater than the growth in the Medicare dialysis population. The dialysis industry opened facilities in more counties across the country, although a greater number of facilities were available to beneficiaries in urban counties than in rural counties.<sup>12</sup> In addition, while almost all facilities provided hemodialysis, fewer facilities provided home dialysis.

In 2001, we estimate that overall Medicare payments to freestanding dialysis facilities exceeded their Medicare-allowable costs, that is, their reasonable costs for services directly related to medical care for beneficiaries, by 3 percent. However, payments were less than costs for small facilities. While we estimate that composite rate payments were 11 percent lower than the costs of providing composite rate services, payments for separately billed drugs were 16 percent higher than the costs of those drugs. Because of this imbalance, providers have an incentive to

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<sup>12</sup>We defined a county as urban if it was in a metropolitan statistical area and as rural if it was outside a metropolitan statistical area, as determined by the Office of Management and Budget.

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maximize the use of profitable separately billed drugs to compensate for inadequate payments under the composite rate.

Daily hemodialysis appears promising for improving patient outcomes. However, studies on the subject are limited in size and scope. Definitive conclusions on the extent to which daily hemodialysis improves patient care cannot be determined from the existing data.

In commenting on a draft of this report, CMS generally agreed with our findings and our conclusion that all outpatient dialysis services should be bundled into a single prospective payment amount based on facilities' allowable costs. Although in the draft report we had also recommended that CMS redesign the prospective payment system for dialysis facilities to bundle the costs of services, including separately billed drugs, into one payment amount, in its comments CMS noted that it would not have the statutory authority to implement such a system. CMS also noted that MMA requires the Secretary of HHS to report to the Congress by October 1, 2005, on the elements and features necessary in the design and implementation of a broader prospective payment system. The Secretary is also required to conduct a 3-year demonstration project, beginning January 1, 2006, that uses a payment system incorporating patient characteristics identified in the report. As a result, we deleted the recommendation in the draft report.

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## Background

Individuals with ESRD are eligible for Medicare benefits regardless of their age.<sup>13</sup> In 2001, Medicare covered about 90 percent of the 406,000 individuals with the disease. ESRD occurs when an individual's kidneys have regressed to less than 10 percent of normal baseline function. Without functioning kidneys, excess wastes and fluids in the body rise to dangerous levels, and certain hormones are no longer produced. The lack of one such hormone, erythropoietin, results in anemia, a condition in which an insufficient number of red blood cells are available to carry oxygen throughout the body. Diabetes and hypertension are the two principal causes of ESRD.

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<sup>13</sup>Generally, to be eligible for benefits under Medicare, a person with ESRD must be (1) entitled to a monthly insurance benefit under Title II of the Social Security Act (or an annuity under the Railroad Retirement Act), (2) fully or currently insured under Social Security, or (3) the spouse or dependent child of a person who meets at least one of the first two requirements. 42 U.S.C. § 426-1(2000).

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## ESRD Population Growth

The ESRD population has grown steadily over the years and is expected to continue to increase. From 1991 through 2001, the total number of individuals with ESRD increased from about 201,000 to 406,000, with an average annual growth rate of 7 percent. While the growth rate declined to about 5 percent in the late 1990s as a result of better preventive treatments, experts believe this decline to be temporary. Increases in the African-American and Hispanic populations, which have particularly high rates of diabetes, are expected to overwhelm this trend and lead to even greater growth rates in the future.<sup>14</sup>

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## Renal Dialysis Treatment

In order to survive, individuals with ESRD require kidney transplantation or dialysis, a process in which excess fluids and wastes are removed from the blood. In 2001, about 292,000, or 72 percent, of all individuals with ESRD underwent dialysis, while the remaining 28 percent, or about 114,000 individuals, were transplant recipients. Transplantation is not a practical option for most individuals with ESRD because suitable donated organs are scarce. Also, many individuals are older and less healthy by the time they develop irreversible kidney failure, making them medically unsuitable for transplant. From 1991 through 2001, the total number of dialysis patients increased at an average annual growth rate of about 7 percent, the same as the ESRD population overall.

In 2001, most dialysis patients received services from one of almost 4,000 hospital-based or freestanding dialysis facilities located in the 50 states and the District of Columbia. These facilities provide hemodialysis, as well as drugs and related clinical and support services for patients who dialyze at home or in a facility. In addition, some facilities provide training for home dialysis and may furnish the equipment and supplies necessary for home dialysis treatment.<sup>15</sup> In 1973, when Medicare benefits were extended to individuals with ESRD, the majority of dialysis facilities were owned and operated by hospitals. By 2001, however, almost 84 percent of all dialysis facilities nationwide were freestanding. In addition, for-profit dialysis facility chains have represented an increasing share of the market. By 2001, the four largest for-profit chains accounted for about two-thirds

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<sup>14</sup>See Xue, et al., "Forecast of the Number of Patients with End-Stage Renal Disease in the United States to the Year 2010."

<sup>15</sup>Instead of receiving equipment and supplies from a facility, beneficiaries may choose to order them through a supplier. Beneficiaries choosing this option still receive the ancillary clinical and social services from a facility.

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of all freestanding facilities, and they provided treatment to about two-thirds of all dialysis patients.

Dialysis can be administered using two methods: hemodialysis and PD. During hemodialysis, a dialysis machine pumps blood through an artificial kidney, called a hemodialyzer, and returns the cleansed blood to the body. Hemodialysis is usually administered three times a week at a dialysis facility, although patients may choose to undergo hemodialysis at home with the assistance of a caregiver. In-facility hemodialysis has become the dominant treatment method since the introduction of dialysis in the 1960s. In 2001, about 90 percent of all dialysis patients underwent in-facility hemodialysis, and less than 1 percent underwent hemodialysis at home.

In PD, the peritoneal membrane, which surrounds a patient's abdomen, acts as a natural blood filter, thus eliminating the need for blood to leave the body and filter through a machine. Patients remove the wastes and excess fluids from their abdomen manually throughout the day, or a machine automates the process while they sleep at night. Unlike hemodialysis, these patients generally dialyze at home. PD became an alternative to hemodialysis in the 1970s, and utilization peaked in the early 1990s, when more than 15 percent of all dialysis patients used this treatment method. By 2001, however, utilization had declined to about 8 percent of the dialysis population.

Hemodialysis performed five to seven times per week, referred to as "daily hemodialysis," more closely approximates the body's continuous cleansing of the blood than the conventional regimen of three hemodialysis treatments per week. Between dialysis treatments, excess wastes and fluids build up in the patient's blood, and many dialysis patients experience side effects such as hypertension, anemia, and low energy levels, which may adversely affect their clinical outcomes and quality of life. Because of these side effects, dialysis patients have high rates of hospitalization and often take several medications. Daily hemodialysis can take place either at home or in a facility, and proponents have asserted that it leads to improved quality of life, fewer hospitalizations, reduced use of medications, and overall cost savings to Medicare.

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## Medicare Payment

Since 1983, Medicare has paid dialysis facilities a composite rate for each dialysis treatment it administers, generally up to a maximum of three treatments per beneficiary per week. The composite rate is a prospectively determined payment amount designed to cover the cost of services associated with a single dialysis treatment, including nursing and other

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clinical services, social services, supplies, equipment, and certain laboratory tests and drugs.<sup>16</sup> Because the composite rate is prospectively determined, providers receive a fixed payment regardless of how much the services actually cost them to deliver. The initial fixed payment amount was derived from the median costs of providing medical services to beneficiaries across a sample of dialysis facilities. A prospective payment methodology encourages providers to control the costs and utilization of the services they provide, as they retain any difference between the payment and their costs.

In 1972, 40 percent of all dialysis patients underwent hemodialysis at home. In 1981, the Congress passed legislation establishing a new system for the payment of outpatient dialysis services for Medicare beneficiaries. The changes were designed to reduce program costs by encouraging home dialysis rather than in-facility dialysis. Under the system, a single prospectively determined rate was implemented for home and in-facility dialysis.<sup>17</sup> However, the percentage of patients who undergo dialysis at home has declined since 1983, the year the composite rate was implemented. In 1983, the proportion of dialysis patients dialyzing at home, whether with hemodialysis or PD, was 12 percent. By December 31, 2001, less than 9 percent of dialysis patients dialyzed at home.

The composite rate has changed minimally since 1983, when the rate averaged about \$131 for hospital-based facilities and \$127 for freestanding facilities. The Congress passed legislation that decreased the rate by \$2 in 1986 and increased it in 1991, 2000, and 2001<sup>18</sup> to about \$135 for hospital-based facilities and \$131 for freestanding facilities. From its implementation in 1983 through the end of 2003, the real dollar value of the composite rate declined by about 65 percent. The dialysis industry remained profitable under this relatively flat payment by increasing efficiency and productivity. However, industry representatives state that efficiency or productivity improvements can no longer make up for the

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<sup>16</sup>Facilities receive a supplemental payment for training beneficiaries on home hemodialysis or PD. The facility receives a composite rate payment for the dialysis services and an additional amount for costs associated with training, such as the instruction beneficiaries receive from facility staff while dialyzing.

<sup>17</sup>Pub. L. No. 97-35, § 2145, 95 Stat. 357, 799-800. *See* H. Conf. Rep. No. 97-208, at 948-9 (1981).

<sup>18</sup>MMA increases the composite rate by 1.6 percent for services furnished on or after January 1, 2005. *See* Pub. L. No. 108-173, § 623(a), 117 Stat. 2066, 2315.

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lack of payment increases. They also state that although the number of dialysis facilities has been increasing throughout the last decade, declining profits may reverse that trend and eventually lead to decreased access for Medicare beneficiaries.

While the composite rate was intended to pay for all services associated with dialysis treatment, Medicare pays separately for certain drugs and laboratory tests that have become routine treatments since 1983. These drugs include, but are not limited to, epoetin (EPO), vitamin D, and iron. Medicare's payment for EPO, a bioengineered protein that substitutes for erythropoietin and is used to treat anemia, is statutorily set at \$10 for every 1,000 units administered;<sup>19</sup> all other separately billed drugs are paid at 95 percent of their average wholesale price (AWP).<sup>20</sup> The Medicare composite rate includes payment for 16 laboratory tests deemed to be routine for dialysis patients. For any of the approximately 1,350 other laboratory tests that beneficiaries may receive, payment is made under a fee schedule to the clinical laboratory that performs the test.

Although facilities are paid under a prospective payment system, CMS requires them to complete annual cost reports that are consistent with Medicare cost principles. These reports include cost information for separately billed drugs as well as items paid through the composite rate. Medicare cost principles were designed to ensure that Medicare pays for the expenses related to medical care for beneficiaries, and that those costs are reasonable and allowable.<sup>21</sup> The agency periodically audits cost reports to remove unreasonable and nonallowable costs and, in the past, has calculated the difference between facility costs as reported on the cost reports and their allowable costs, referred to as an audit adjustment. The

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<sup>19</sup>42 U.S.C. § 1395rr (b)(11)(B)(ii)(2000). While the Secretary of HHS is authorized to adjust this payment, it has remained the same since 1994.

<sup>20</sup>MMA changed Medicare's payment formula for drugs. In general, payments for outpatient drugs furnished in 2004 will equal 85 percent of AWP. Separately billed drugs furnished in connection with dialysis services will continue to be paid at 95 percent of AWP in 2004. *See* Pub. L. No. 108-173, § 303(b), 117 Stat. 2066, 2238.

<sup>21</sup>An example of a nonallowable Medicare cost is the cost of transporting beneficiaries to and from a dialysis facility, because transportation is not directly related to medical care. The salary of a facility administrator is an example of a cost that is allowable but, depending upon the salary amount, may not be reasonable. For example, in most instances, the Medicare compensation for a facility administrator may not exceed \$90,000. If a facility claims \$100,000 as compensation, Medicare would consider \$10,000 of the amount as an unreasonable cost, unless the facility can justify a compensation rate over the \$90,000 limit.



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Balanced Budget Act of 1997 required the agency to audit dialysis facility cost reports, beginning in 1996, at least once every 3 years.<sup>22</sup>

In recent years, the Congress has moved toward a broader payment bundle for dialysis services. In 2000, BIPA required the Secretary of HHS to develop a payment system that includes clinical laboratory tests and drugs that are routinely used, but are currently billed separately from dialysis treatment.<sup>23</sup> BIPA also required the Secretary to submit a report and recommendations on this system to the Congress. CMS issued the report in 2003, concluding that currently available data appear sufficient to expand the payment bundle to include those services.<sup>24</sup> In December 2003, MMA mandated that effective January 1, 2005, a payment system be implemented combining the composite rate payment with the amount by which payments for separately billed drugs exceed their acquisition costs. Drugs that are currently paid separately will continue to be paid outside this system. This system must adjust for certain beneficiary characteristics and geographic differences in cost.<sup>25</sup> In addition, the Secretary is required to submit a report to the Congress by October 1, 2005, that details the elements and features for the design and implementation of a bundled payment system including certain drugs that are currently billed separately. The Secretary is then required to establish a 3-year demonstration project, beginning January 1, 2006, using a payment system that accounts for patient characteristics identified in the report.

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<sup>22</sup>Pub. L. No. 105-33, § 4558(a), 111 Stat. 251, 463.

<sup>23</sup>Pub. L. No. 106-554, App. F, § 422(c)(1), 114 Stat. 2763A-517.

<sup>24</sup>U.S. Department of Health and Human Services, *Toward a Bundled Outpatient Medicare End-Stage Renal Disease Prospective Payment System* (Baltimore, Md.: 2003).

<sup>25</sup>Pub. L. No. 108-173, § 623(d), 117 Stat. 2066, 2313-14.



## Dialysis Facilities Increased at Same Rate as Beneficiary Population, but Supply Varied Geographically and by Treatment Method

From 1998 through 2001, the total number of hospital-based and freestanding dialysis facilities increased at about the same rate as the Medicare dialysis population, and the total number of dialysis stations, or treatment areas devoted to providing dialysis to patients, increased at a greater rate than the Medicare dialysis population. The dialysis industry opened facilities in more counties across the country, although the number of facilities available to beneficiaries living in urban counties was greater than in rural counties. In addition, while almost all facilities provided hemodialysis, fewer facilities provided home dialysis.

## Growth in Number of Dialysis Facilities Kept Pace with Growth in Beneficiary Population

Based on our analysis of the CMS Facility Survey files, the total number of hospital-based and freestanding dialysis facilities increased from 3,415 to 3,960, or about 16 percent, from December 31, 1998, through December 31, 2001. Over the same period, the number of ESRD beneficiaries on dialysis increased about 15 percent. While the annual growth in facilities slowed each year, this occurred primarily because of a decrease in new facilities, not because of an increase in closures. From 1998 through 2001, the number of facilities closing each year amounted to less than 1 percent of those that were operating at the end of that year.

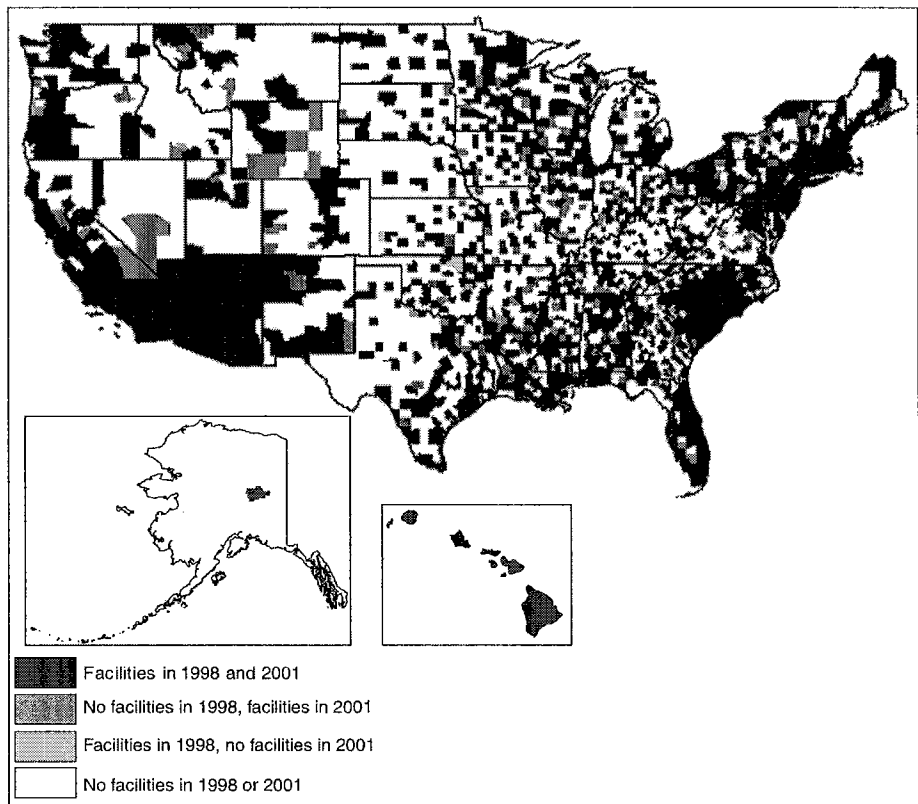
Because facilities vary in size, a more specific indicator of their capacity to provide hemodialysis is the number of dialysis stations in use at dialysis facilities. From December 31, 1998, through December 31, 2001, we estimate that the number of stations increased by over 24 percent, from about 53,100 to about 66,100, exceeding the growth rate of the dialysis population. The annual growth rate of stations was over 10 percent in 2001, much higher than the 5 percent growth rate of the Medicare dialysis population in that year.

In addition, the dialysis industry expanded services to a larger portion of the country. The percentage of counties that had at least one dialysis facility increased from 41 to 47 percent, so that a total of 1,466 counties<sup>26</sup> had at least one dialysis facility in 2001 (see fig. 1). While another 1,599 counties had at least one beneficiary on dialysis but no facility in 2001, most of these counties were adjacent to at least one other county that had a dialysis facility. Of the counties that were not adjacent to another county

<sup>26</sup>In 2001, there were a total of 3,140 counties in the 50 states. In addition, we include the District of Columbia as a county.

with a facility, many were concentrated in areas of the West and Midwest. Beneficiaries living in these counties either traveled to another facility or dialyzed at home.

**Figure 1: Dialysis Facilities by County, 1998-2001**



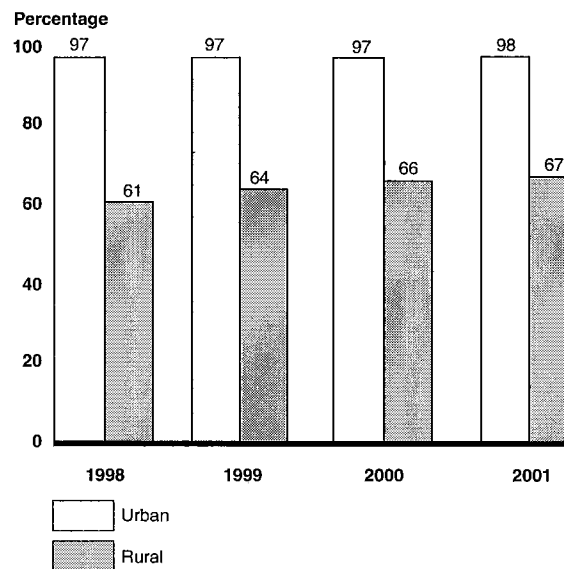
Source: GAO analysis of CMS data.

The supply of facilities in counties with beneficiaries on dialysis has remained stable. The percentage of beneficiaries on dialysis who resided in counties with at least one facility increased from 89 to 91 percent from 1998 through 2001. In addition, the average number of facilities per county, weighted by the number of beneficiaries in each county, increased from 11 to 12 from 1998 through 2001, as did the weighted average number of stations, which rose from 201 to 234.

## More Dialysis Facilities Available in Urban Counties Than in Rural Counties

While overall beneficiary access to dialysis facilities remained stable, more facilities are available to beneficiaries on dialysis who reside in urban counties than to beneficiaries on dialysis in rural counties. From 1998 through 2001, the percentage of urban beneficiaries with at least one facility in their counties increased slightly from 97 to 98 percent, while the percentage of rural beneficiaries with at least one facility in their counties increased, but remained much lower, from 61 to 67 percent (see fig. 2).

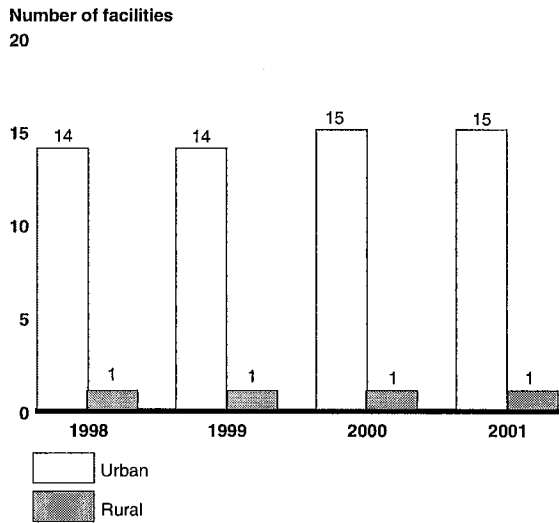
**Figure 2: Percentage of Beneficiaries on Dialysis Who Reside in Counties with at Least One Facility, 1998-2001**



Source: GAO analysis of CMS data.

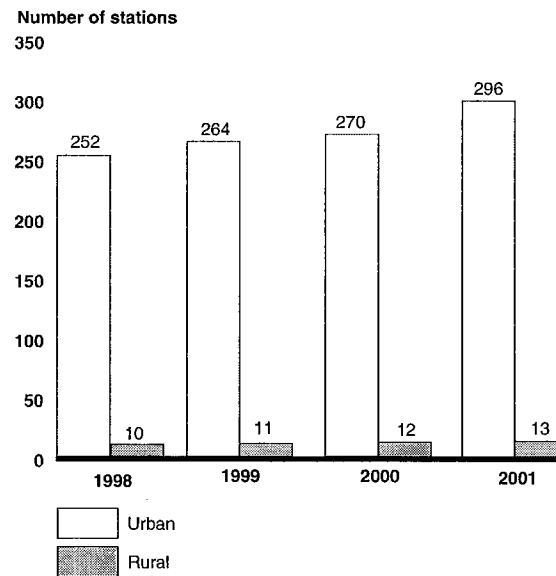
Furthermore, beneficiaries on dialysis residing in urban counties had more dialysis facilities available in their counties. From 1998 through 2001, the average number of facilities per urban county, weighted by the number of beneficiaries in each county, increased from 14 to 15 (see fig. 3), and the weighted average number of stations increased from 252 to 296 (see fig. 4). From 1998 through 2001, the weighted average number of facilities per rural county remained at 1, although the weighted average number of stations increased from 10 to 13.

**Figure 3: Average Number of Facilities Available per County, by Location, 1998-2001**



Source: GAO analysis of CMS data.

Note: Averages are weighted by the number of beneficiaries in each county.

**Figure 4: Average Number of Stations Available per County, by Location, 1998-2001**

Source: GAO analysis of CMS data.

Note: Averages are weighted by the number of beneficiaries in each county.

Across rural areas, substantial variation may exist in the supply of dialysis facilities. For example, 73 percent of beneficiaries on dialysis in Florida's 33 rural counties had at least one facility in their counties in 2001, while only 39 percent of beneficiaries on dialysis in Michigan's 58 rural counties had at least one facility in their counties. Although such differences could potentially be explained by differences in the geographic size of rural counties, rural counties in both Michigan and Florida average roughly 695 square miles.

The number of dialysis facilities may be lower or nonexistent in certain geographic locations for certain reasons. The population of beneficiaries on dialysis is relatively small, and it may not be financially feasible to operate facilities in areas that do not have a sufficient number of beneficiaries needing dialysis. For example, while nearly 73 percent of counties were designated as rural in 2001, only 22 percent of beneficiaries on dialysis lived in those counties; about half of all rural counties were home to 15 or fewer beneficiaries on dialysis. Also, many industry representatives we interviewed stated that it was difficult to recruit and retain nurses to staff facilities. Shortages of nurses can hamper the

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industry's ability to open facilities or keep facilities sufficiently staffed in certain geographic areas.

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**Number of Facilities  
Providing Home Dialysis  
Much Lower Than Number  
of Facilities Providing  
Hemodialysis**

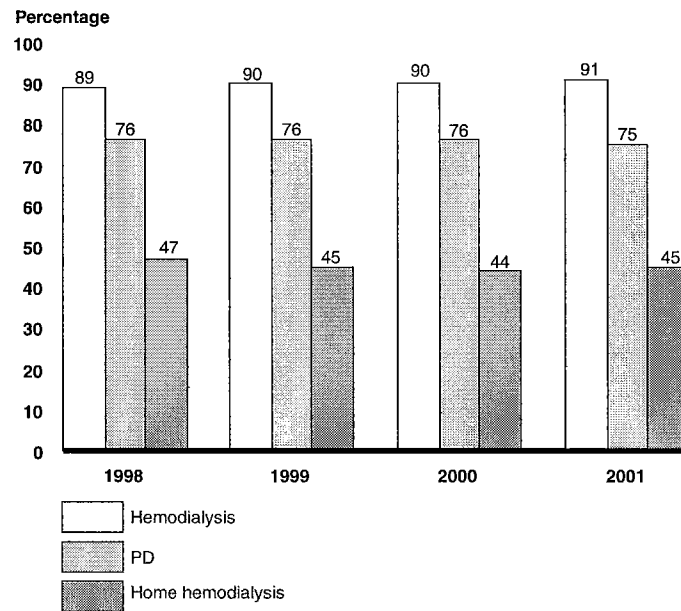
Dialysis facilities provided in-facility hemodialysis almost universally, but the number of facilities providing home dialysis (PD and home hemodialysis) was much lower and declining. According to our analysis of the CMS Facility Survey files, 98 percent of dialysis facilities provided hemodialysis each year from 1998 through 2001. Over the same period, the percentage of dialysis facilities providing PD decreased from 46 to 40 percent, and the percentage of dialysis facilities providing home hemodialysis decreased from 10 to 8 percent.

Beneficiaries on dialysis also had more facilities available in their counties that provided hemodialysis than home dialysis.<sup>27</sup> The percentage of beneficiaries on dialysis who had a facility providing hemodialysis in their counties increased from 89 to 91 percent from 1998 through 2001 (see fig. 5). In contrast, the percentage of beneficiaries on dialysis who had a facility providing PD in their counties slightly decreased, from 76 to 75 percent, and the percentage of beneficiaries on dialysis who had a facility providing home hemodialysis in their counties declined from 47 to 45 percent. From 1998 through 2001, the average number of facilities providing hemodialysis per county, weighted by the number of beneficiaries in each county, increased slightly from 10 to 12 (see fig. 6). Over the same period, the weighted average number of facilities providing PD per county fell from 6 to 5, and on average, only 1 facility per county provided home hemodialysis.

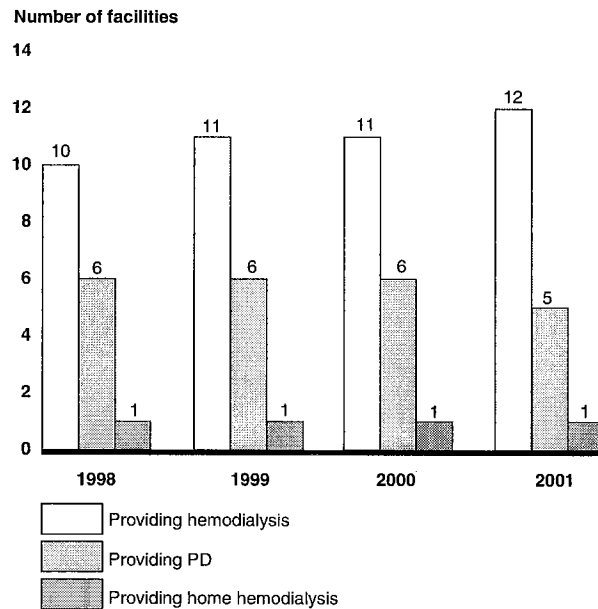
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<sup>27</sup>Proximity to a facility is somewhat less critical for beneficiaries who perform home dialysis because they are not required to regularly visit a facility for dialysis treatments.

**Figure 5: Percentage of Beneficiaries on Dialysis Who Had a Treatment Method Available in Their Counties, 1998-2001**



Source: GAO analysis of CMS data.

**Figure 6: Average Number of Facilities Available per County, by Treatment Method, 1998-2001**

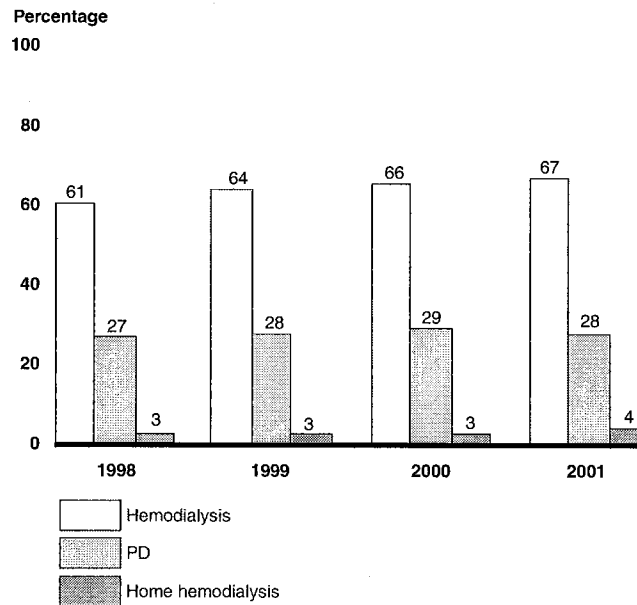
Source: GAO analysis of CMS data.

Note: Averages are weighted by the number of beneficiaries in each county.

In rural counties, the number of facilities offering home dialysis remained low. From 1998 through 2001, the percentage of rural beneficiaries on dialysis with a facility providing hemodialysis in their counties increased from 61 to 67 percent (see fig. 7). In contrast, the percentage of rural beneficiaries on dialysis with a facility providing PD increased slightly from 27 to 28 percent, and the percentage of rural beneficiaries with a facility providing home hemodialysis increased from 3 to 4 percent. Beneficiaries on dialysis in rural counties had a weighted average of one facility providing hemodialysis per county and no facility providing PD or home hemodialysis. In addition, there were rural counties with beneficiaries on dialysis but no facilities. These beneficiaries dialyzed either in a neighboring county or at home.



**Figure 7: Percentage of Beneficiaries on Dialysis in Rural Counties Who Had a Treatment Method Available in Their Counties, 1998-2001**



Source: GAO analysis of CMS data.

The number of facilities providing home dialysis may have been low for several reasons. Some providers and nephrologists we interviewed stated that many physicians are either unfamiliar with home dialysis or believe that patients have better outcomes with in-facility hemodialysis. They also reported that home programs are often not financially feasible for facilities unless there is a substantial number of patients receiving the treatment method, because facilities must hire staff to train and manage the care of these patients. Some providers and nephrologists also stated that facilities have a financial disincentive to provide home dialysis, because greater utilization of PD may result in unused hemodialysis stations and may reduce the need for certain profitable drugs like EPO. They also reported that PD may be favorable for beneficiaries in rural areas, where facilities can be more distantly located.

## Total Medicare Payments to Freestanding Dialysis Facilities Exceeded Costs, but Current Payment Methodology Is Not Appropriate

We estimate that after adjusting to exclude nonallowable costs, total payments to freestanding dialysis facilities exceeded providers' costs in 2001. Although payments were higher than costs overall, payments to small facilities were lower than costs. In addition, while composite rate payments were well below the costs of those services, separately billed drug payments far exceeded the costs of those services. Because of this imbalance in the payment structure, providers have an incentive to maximize the use of profitable separately billed drugs to compensate for inadequate payments under the composite rate.

## Payments to Freestanding Facilities Generally Exceeded Allowable Costs, but Small Facilities Were an Exception

We estimate that Medicare payments to freestanding dialysis facilities exceeded their Medicare-allowable costs by 3 percent, on average. In order to calculate this percentage, we used costs as reported on dialysis facilities' cost reports and used an adjustment to exclude nonallowable costs. Before the adjustment, we estimate that on average, payments were 1 percent below costs, a payment-to-cost ratio of 0.99,<sup>28</sup> for composite rate services and separately billed drugs in 2001. Past agency audits have demonstrated that dialysis facilities have included nonallowable costs in their cost reports. The Health Care Financing Administration (HCFA) conducted audits of a random sample of 1988 and 1991 dialysis facility cost reports and found that providers' allowable costs were about 90 percent and 89 percent, respectively, of reported costs. HCFA also audited the 1996 reports but did not calculate a similar percentage of reported costs that were allowable.<sup>29</sup> When MedPAC compared the 1996 cost reports before and after auditing, it found that the allowable cost per treatment for composite rate services and separately billed drugs for freestanding facilities was about 96 percent of the reported cost per treatment.<sup>30</sup> Because providers have historically included nonallowable costs on their cost reports, we applied MedPAC's adjustment, which is the most conservative and most recent adjustment, to our payment-to-cost ratio of 0.99 and derived an adjusted payment-to-cost ratio of 1.03 for 2001.

<sup>28</sup> A payment-to-cost ratio of 1.00 indicates that payments equal costs. A ratio above 1.00 indicates that payments are greater than costs and below 1.00 indicates that payments are lower than costs.

<sup>29</sup> CMS is currently auditing the 2001 cost reports and expects to complete this task in 2005.

<sup>30</sup> Medicare Payment Advisory Commission, March 2003.

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Although we calculated an overall payment-to-cost ratio for 2001 only,<sup>31</sup> MedPAC has reported a decrease in these ratios from 1.14 in 1996 to 1.04<sup>32</sup> in 2001.<sup>33</sup>

Although payments exceeded costs overall in 2001, they did not exceed costs for all sizes of facilities. For example, payments were well below allowable costs for small facilities,<sup>34</sup> with an adjusted payment-to-cost ratio of 0.91 (see table 1).<sup>35</sup> Given the fixed costs a facility incurs in terms of staffing, equipment, supplies, and rent, revenue from the small patient base in these facilities may not be sufficient to meet costs.

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<sup>31</sup>We were unable to determine a payment-to-cost ratio for the composite rate and separately billed drugs before 2001 because, prior to July 1, 2000, the Medicare outpatient claims data contained payment information for all services included on the claim but not for each individual service.

<sup>32</sup>Our 2001 payment-to-cost ratio differs from MedPAC's ratio because we used a more recent version of the 2001 cost report file.

<sup>33</sup>Medicare Payment Advisory Commission, March 2003.

<sup>34</sup>We defined the size of the facility based on the 25th and 75th percentiles of total dialysis treatments. Small facilities are those reporting a number of dialysis treatments less than the 25th percentile, medium facilities are those reporting a number of dialysis treatments greater than or equal to the 25th percentile and less than or equal to the 75th percentile, and large facilities are those reporting a number of treatments greater than the 75th percentile.

<sup>35</sup>From the 1996 cost reports, MedPAC also calculated that the allowable cost per treatment for composite rate services and separately billed drugs for small and large freestanding facilities was 97 percent of the reported cost per treatment and for medium freestanding facilities was 96 percent of the reported cost per treatment. Our definition of size and MedPAC's definition of size are the same. (Medicare Payment Advisory Commission, March 2003.)

**Table 1: Freestanding Dialysis Facility Adjusted Payment-to-Cost Ratios for Composite Rate Services and Separately Billed Drugs, Overall and by Size, 2001**

<b>Facilities</b>	<b>Overall payment-to-cost ratio</b>
<b>All</b>	<b>1.03</b>
Small	0.91
Medium	1.02
Large	1.05

Source: GAO analysis of CMS data.

Notes: Payment-to-cost ratios among facilities in the 50 states and the District of Columbia. Ratios are weighted by total Medicare payments received by each facility. A payment-to-cost ratio of 1.00 indicates that payments equal costs. A ratio above 1.00 indicates that payments are greater than costs and below 1.00 indicates that payments are lower than costs. We defined the size of the facility based on the 25th and 75th percentiles of total dialysis treatments. Small facilities are those reporting a number of dialysis treatments less than the 25th percentile, medium facilities are those reporting a number of dialysis treatments greater than or equal to the 25th percentile and less than or equal to the 75th percentile, and large facilities are those reporting a number of treatments greater than the 75th percentile.

## Current Payment Methodology Is Not Appropriate

The Medicare payment methodology for dialysis services is not appropriate. In 2001, composite rate payments to freestanding facilities, intended to cover the costs of a variety of services associated with a dialysis treatment, such as nursing, supplies, social services, and certain laboratory tests, were well below the costs of those services. In addition, the composite rate does not include all the services beneficiaries on dialysis typically receive, and does not account for variation in service utilization and costs among beneficiaries. Separately billed drug payments, however, far exceeded the costs of those items. Because utilization of separately billed drugs is largely unconstrained,<sup>36</sup> providers have an incentive to overutilize them to compensate for lower payments under the composite rate. In addition, composite rate payments for home dialysis treatments far exceeded the costs of those services, but payments for home dialysis training were well below the costs of those services.

We estimate that from 1998 through 2001, composite rate payments were well below the costs of composite rate services. During these years, the

<sup>36</sup>While facilities must report specific clinical indicators in order to provide EPO to beneficiaries, other separately billed drugs are administered when they are deemed medically necessary by the physician.

unadjusted<sup>37</sup> payment-to-cost ratio for composite rate services was below 1.00 and steadily decreased every year, falling from 0.94 to 0.89 (see table 2).

**Table 2: Freestanding Dialysis Facility Unadjusted Payment-to-Cost Ratios for Composite Rate Services, 1998-2001**

	1998	1999	2000	2001
Payment-to-cost ratio	0.94	0.93	0.91	0.89

Source: GAO analysis of CMS data.

Notes: Payment-to-cost ratios among facilities in the 50 states and the District of Columbia. Ratios are weighted by total Medicare payments received by each facility. A payment-to-cost ratio of 1.00 indicates that payments equal costs. A ratio above 1.00 indicates that payments are greater than costs and below 1.00 indicates that payments are lower than costs.

Furthermore, the composite rate does not pay for all services routinely provided during a dialysis session. While the composite rate was designed to pay for services associated with a single dialysis session, certain items or services introduced since the creation of the rate are paid separately. We determined that three separately billed drugs, EPO, vitamin D, and iron, and drug-related supplies were provided to most dialysis beneficiaries and frequently accompanied hemodialysis treatments (see table 3). For example, 98 percent of beneficiaries received EPO in 2001 and, on average, at every dialysis treatment.

<sup>37</sup>MedPAC's adjustment to exclude nonallowable costs specifically applies to the combined costs of composite rate services and separately billed drugs. Therefore, we did not apply this adjustment to the payment-to-cost ratios for either the composite rate or separately billed drugs individually, and refer to those ratios as unadjusted.

**Table 3: Most Frequent Items Billed Separately in Association with Hemodialysis, 2001**

Item	Percentage of beneficiaries <sup>a</sup> receiving item	Frequency of billing among beneficiaries receiving item <sup>b,c</sup>
EPO	98	Every treatment
Drug-related supplies	84	Every 9th treatment
Iron	79	Every 17th treatment
Vitamin D	70	Every 9th treatment
Hepatitis B vaccine	25	Every 60th treatment
Vancomycin	24	Every 50th treatment
Levocarnitine	5	Every 12th treatment

Source: GAO analysis of CMS data.

<sup>a</sup>Beneficiaries receiving in-facility hemodialysis.

<sup>b</sup>Medicare instructs providers to record each drug administration on the claim separately, and accordingly, we defined one administration of a drug as one record on the claim. Some providers may aggregate the units of several administrations as one record. To the extent this is the case, the billing frequencies for these specific drugs likely underestimate the actual administration frequencies.

<sup>c</sup>Per in-facility hemodialysis treatment. Beneficiaries typically receive 3 treatments per week, or about 13 per month.

The composite rate also does not adjust for factors that may affect the cost of providing dialysis services.<sup>38</sup> Providers we interviewed told us that certain beneficiaries require more services than others because of the presence of conditions including diabetes, hypertension, vascular access problems,<sup>39</sup> and other physical impairments. They stated that care for these beneficiaries may be more costly due to additional staff time, additional resources, or more frequent dialysis. There is currently no adjustment to the composite rate to account for variation in the costs of providing services to beneficiaries who consume more resources than average.

While composite rate payments were well below costs, we estimate that payments for separately billed drugs far exceeded the costs of those drugs

<sup>38</sup>The only adjustment to the composite rate accounts for variation in area wages.

<sup>39</sup>In order to filter a patient's blood during hemodialysis, the vascular system, or bloodstream, must be accessed through a fistula, graft, or catheter. The access site must be continually maintained to help prevent complications, such as narrowing of the blood vessel or infection of the site.

in 2001, with an unadjusted payment-to-cost ratio of 1.16. Because utilization of separately billed drugs is largely unconstrained and because payments for these items exceeded costs, providers have an incentive to overutilize them. Representatives from one of the largest chain providers and several nephrologists we interviewed reported that this incentive to overutilize exists because separately billed drug payments compensate for losses on composite rate services. However, several nephrologists and researchers we interviewed also reported that beneficiaries who undergo PD, or who otherwise dialyze more frequently than three times per week, have a reduced need for separately billed drugs.

In addition to the imbalance in payment between composite rate services and separately billed drugs, an imbalance exists between payments for home dialysis treatments and home dialysis training. Two industry representatives and representatives of a patient advocacy organization we interviewed stated that Medicare payments for home dialysis training do not cover the costs of the service. We found that in 2001, the unadjusted payment-to-cost ratio for composite rate payments for home dialysis treatments was 1.11 and for home dialysis treatments and training combined was 1.04.<sup>40</sup> The unadjusted payment-to-cost ratio for composite rate payments for home dialysis training alone was 0.38, indicating that payments were well below costs. A perception that facilities are losing money on the initial home dialysis training, even though payments are above costs for the training and treatment combined, may serve as a disincentive to offering the home dialysis treatment method.

## Daily Hemodialysis Appears Promising, but Rigorous Data Are Lacking

Daily hemodialysis, which is performed five to seven times per week, may improve patients' clinical outcomes and quality of life because it more closely approximates the body's continuous cleansing of the blood. The literature indicates that daily hemodialysis patients have a greater amount of toxin removed from their bodies, or a more adequate dialysis dosage, than conventional hemodialysis patients.<sup>41</sup> Dialysis dosage is important because research suggests that inadequate dosage correlates with increased mortality. In addition, studies report that anemia and

<sup>40</sup>Providers' separately billed drug costs are not reported by treatment method on the cost report, and therefore, we cannot calculate payment-to-cost ratios for the composite rate and separately billed drugs together by treatment method.

<sup>41</sup>For example, see J. Traeger, et al., "Daily Versus Standard Hemodialysis: One Year Experience," *Artificial Organs*, vol. 22, no. 7 (1998): 558-563.

malnutrition, two serious conditions associated with increased morbidity and mortality, improve with daily hemodialysis,<sup>42</sup> as does patient quality of life.<sup>43</sup> For example, patients on daily hemodialysis experience less fatigue and enjoy a wider range of dietary choices. Studies also report that patients on daily hemodialysis have a reduced need for medication, including EPO<sup>44</sup> and drugs to control blood pressure,<sup>45</sup> and a reduced number of hospitalizations.<sup>46</sup>

Although studies on daily hemodialysis report improvements in patient outcomes, these studies are limited in size and scope. The daily hemodialysis patient base is extremely small, given that few dialysis facilities provide the treatment, and those that do have few patients using it. Although no national data exist on the utilization of daily hemodialysis, nephrologists we spoke with who provide daily hemodialysis estimate that approximately 200 patients are undergoing the treatment nationwide. Published studies are principally nonrandomized and have small sample sizes, typically fewer than 25 patients, and therefore do not provide definitive evidence supporting the treatment. Specifically, studies do not evaluate whether observed improvements in mortality can be attributed to the treatment itself or to some other factor. To definitively assess the treatment, more rigorous data are needed.

Dialyzing more frequently has drawbacks. Although patients may experience better outcomes, daily hemodialysis increases the number of times a patient connects to the hemodialysis machine, and may increase transportation costs if a patient chooses to dialyze at a facility rather than at home. Such increased burdens may outweigh the benefits for a

<sup>42</sup>For an example of improvements in anemia, see J.D. Woods, et al., "Clinical and Biochemical Correlates of Starting 'Daily' Hemodialysis," *Kidney International*, vol. 55, no. 6 (1999): 2467-2476. For an example of improvements in malnutrition, see R. Galland, et al., "Short Daily Hemodialysis Rapidly Improves Nutritional Status in Hemodialysis Patients," *Kidney International*, vol. 60, no. 4 (2001): 1555-1560.

<sup>43</sup>For example, see P.F. Vos, et al., "Clinical Outcome of Daily Dialysis," *American Journal of Kidney Diseases*, vol. 37, no. 1, suppl. 2 (2001): S99-S102.

<sup>44</sup>For example, see Vos, et al.

<sup>45</sup>For example, see A. Pierratos, et al., "Nocturnal Hemodialysis: Three-Year Experience," *Journal of the American Society of Nephrology*, vol. 9, no. 5 (1998): 859-868.

<sup>46</sup>For example, see R.S. Lockridge, Jr., et al., "Nightly Home Hemodialysis: Fifteen Months of Experience in Lynchburg, Virginia," *Home Hemodialysis International*, vol. 3 (1999): 23-28.



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significant number of patients. Even so, providers and nephrologists we interviewed estimated that anywhere from 10 to 50 percent of the dialysis population would choose to undergo daily hemodialysis.

Several studies, each of which evaluated the costs of one to two facilities, have found that facility costs increase upon implementation of daily hemodialysis.<sup>47</sup> Industry representatives reported that despite the possible benefits of daily hemodialysis, it is not currently financially feasible to offer it to a large number of Medicare beneficiaries because Medicare does not routinely pay for more than three dialysis treatments per week. However, if beneficiaries who undergo daily hemodialysis have a reduced need for other Medicare services, such as drugs and inpatient stays, the Medicare program may realize overall cost savings.

Research currently being conducted by the National Institutes of Health (NIH) may provide more rigorous data on daily hemodialysis, although it will not determine whether there is an overall cost savings to Medicare. With partial funding from CMS, NIH has funded four centers to test whether it is feasible to randomize a representative sample of patients into either conventional or daily hemodialysis. The trials will track a number of patient outcomes for at least 6 months, including anemia, nutritional status, blood pressure, medication use, and hospitalizations, but they are not designed to enroll enough patients to conclusively determine whether differences in mortality or hospitalizations are significant. Trial results, which will not be available until 2007, will determine whether NIH should continue with a large-scale trial that would measure the impact of more frequent dialysis on mortality or cardiovascular outcomes or both.

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## Concluding Observations

From December 31, 1998, through December 31, 2001, beneficiary access to dialysis facilities and services appeared stable. The total number of dialysis facilities nationwide increased at about the same rate as the Medicare dialysis population, and the total number of stations nationwide increased at a faster rate than the Medicare dialysis population. Over the same period of time, the number of counties with at least one facility increased.

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<sup>47</sup>For example, see P.E. Mohr, et al., "The Case for Daily Dialysis: Its Impact on Costs and Quality of Life," *American Journal of Kidney Diseases*, vol. 37, no. 4 (2001): 777-789.

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On average, Medicare payments to freestanding dialysis facilities for composite rate and separately billed services combined exceeded providers' estimated allowable costs by 3 percent in 2001. However, composite rate payments were well below the costs of composite rate services, and separately billed drug payments far exceeded the costs of separately billed drugs. The current payment methodology gives providers an incentive to overutilize separately billed drugs in order to compensate for losses on composite rate services and does not account for possible cost differences in treating beneficiaries. A payment methodology that bundled the services a facility provides into a prospective payment amount would encourage providers to control the costs and utilization of these items, as they retain the difference if their payments exceed their costs of providing necessary services. A system that is based on allowable costs and accounts for possible cost differences in treating beneficiaries would ensure that Medicare pays appropriately for the efficient delivery of services.

As required by law, CMS is currently designing a bundled prospective payment system. In 2003, CMS reported to the Congress that currently available data appear sufficient to expand the payment bundle to include drugs and other services currently paid separately. MMA requires the Secretary of HHS to issue a second report by October 1, 2005, that details the elements and features for the design and implementation of a bundled system, and then implement a 3-year demonstration project beginning January 1, 2006, that is based on that system.

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## Agency and External Reviewer Comments and Our Evaluation

We received written comments on a draft of this report from CMS (see app. II). We also received technical comments from NIH, which we incorporated where appropriate, and oral comments from seven external reviewers. The external reviewers represented industry and patient organizations. They included the American Association of Kidney Patients (AAKP); the Renal Physicians Association (RPA); Dialysis Clinic, Inc. (DCI), the largest nonprofit dialysis chain; Fresenius Medical Care (FMC), the largest for-profit dialysis chain; the National Kidney Foundation, a foundation for the prevention and treatment of kidney disease; the National Renal Administrators Association (NRAA), which represents employees at dialysis facilities; and the Renal Leadership Council (RLC), an association representing the four largest for-profit dialysis facility chains.

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## CMS Comments and Our Evaluation

In commenting on a draft of this report, CMS generally agreed with our findings and our conclusion that all outpatient dialysis services should be bundled into a single prospective payment amount based on facilities' allowable costs. Although in the draft report we had also recommended that CMS redesign the prospective payment system for dialysis facilities to bundle the costs of services, including separately billed drugs, into one payment amount, in its comments CMS noted that it would not have the statutory authority to implement such a system. CMS also noted that MMA requires the Secretary of HHS to report to the Congress by October 1, 2005, on the elements and features necessary in the design and implementation of a broader payment system. The Secretary is also required to conduct a 3-year demonstration project, beginning January 1, 2006, using a payment system incorporating patient characteristics identified in the report. CMS also asked that we recognize its research on a bundled payment system that has been under way since October 2000. As a result of these comments, we deleted the recommendation in the draft report. In addition, although MMA was discussed in our draft report, we more prominently highlighted it and CMS's research in the report.

CMS also stated that while our findings on beneficiary access were reassuring, it is concerned that we did not specifically address access issues at the regional level. According to CMS, its staff has been told that hospitals in certain regions, such as New England and New York, are having difficulty discharging and placing ESRD patients in dialysis facilities in those areas. We acknowledged in the draft report that supply varied geographically and by treatment method. We based our findings on aggregate indicators, such as trends in numbers of stations and facilities relative to the beneficiary population, which all suggested that access had been stable from 1998 through 2001. We would not have been able to identify the extent to which supply has changed since 2001, as 2001 data were the most recent available at the time of our analysis.

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## Industry and Patient Organization Comments

Comments from the industry representatives and patient organizations centered on three different areas: beneficiary access to dialysis, the data used in our analysis of Medicare payment adequacy, and the appropriateness of the current payment methodology.

Many comments addressed our finding that beneficiary access to dialysis is stable. Five external reviewers stated that Medicare payments are currently inadequate, and due to inadequate payments, facilities are closing in areas where Medicare beneficiaries constitute a high percentage of dialysis patients. RPA specifically was concerned that facilities may try

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to maximize their numbers of private-pay patients and minimize their numbers of Medicare beneficiaries in the future. Three external reviewers asserted that access is currently decreasing due to staffing shortages at available facilities, particularly with respect to nurses. These reviewers also stated that certain minority populations, such as Native Americans, and certain areas of the country, such as rural and inner city areas, are currently experiencing access problems.

Several external reviewers commented on access issues specifically related to home dialysis. NRAA agreed with our finding that payment for home training is inadequate and therefore serves as a barrier to home dialysis. RPA agreed that one reason for low utilization of PD is that PD patients use less of the profitable separately billed drugs. AAKP provided the same assertion and added that the lack of training for nephrologists serves as a barrier to home dialysis.

Industry representatives expressed concerns regarding our payment analysis, specifically the use of data from 2000 and 2001 and our application of an audit adjustment to facility cost data. DCI stated that facility costs have risen since 2001; therefore, our analysis does not reflect current conditions. FMC, RLC, and NRAA stated that using an audit adjustment based on 1996 cost reports does not result in an accurate assessment of costs; they asserted that the amount of nonallowable costs that facilities include on their cost reports has decreased since 1996.

Several groups commented on the appropriateness of the current payment methodology. Two industry representatives, DCI and RLC, acknowledged that an incentive exists to overutilize separately billed drugs in order to compensate for losses on composite rate services, and the physician association, RPA, acknowledged that there is excessive use of these drugs. However, another industry group, NRAA, stated that our assertion that an incentive to overutilize exists was extreme. In addition, four external reviewers were concerned that bundling costs would create an incentive for facilities to either underserve beneficiaries or to accept only those beneficiaries who use relatively few resources. Four external reviewers were concerned that there would be no regular update to the payment rate if a bundled rate was established, which could limit access to new technology.

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## Our Evaluation of Industry and Patient Organization Comments

Concerning the comments that access is decreasing overall, for certain regions and certain populations and for home dialysis, we acknowledged in the draft report that supply may vary geographically and by treatment method. However, also as noted in the draft report, we based our finding that beneficiary access to dialysis is stable on aggregate indicators, such as trends in numbers of stations and facilities relative to the beneficiary population. In particular, we noted that few facilities closed from 1998 through 2001, with the number of facilities closing each year amounting to less than 1 percent of those operating at the end of the year. We were not able to analyze the adequacy of facility staffing due to a lack of adequate data.

With respect to our adjustment of facility cost data, BIPA required that we use audited cost data when analyzing the adequacy of Medicare payment. Although CMS is currently auditing the 2001 cost reports, the agency's last completed audit was of the 1996 cost reports. Given the increase in health care costs over time, we did not believe it was appropriate to assess the adequacy of Medicare payment using only 1996 cost reports. In order to satisfy the requirements of our mandate, we estimated the percentage of costs on the unaudited 2001 cost reports that were Medicare allowable. To do so, we relied on an audit adjustment calculated by MedPAC. MedPAC's adjustment was based on the 1996 cost reports and was lower than the previous two audit adjustments calculated by HCFA in 1988 and 1991. We believe it is appropriate to apply MedPAC's 1996 audit adjustment to 2001 costs because it is the most recent of the last three audit adjustments. We also noted in the draft report that it is the most conservative of the three adjustments.

With respect to our conclusion that the current payment methodology is not appropriate, we acknowledge that a prospective payment could create an incentive to underserve beneficiaries, because providers retain the difference if their payments exceed their costs. However, this incentive exists under all prospective payment systems. If the bundled payment amount is based on facilities' allowable costs of delivering services, and takes into account possible cost differences in treating beneficiaries, facilities will be financially better equipped to deliver the appropriate level of service to each beneficiary.

Industry representatives and patient organizations also raised several issues that went beyond the scope of our report. These issues included whether Medicaid and physician payments are adequate and the Medicare definition of allowable costs.

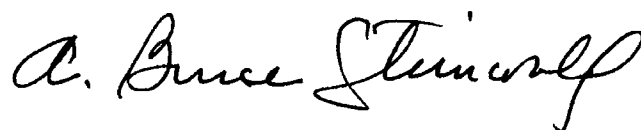
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Reviewers also made technical comments, which we incorporated where appropriate.

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We are sending copies of this report to the Administrator of CMS and appropriate congressional committees. The report is available at no charge on GAO's Web site at <http://www.gao.gov>. We will also make copies available to others on request.

If you or your staffs have any questions, please call me at (202) 512-7119. Another contact and key contributors to this report are listed in appendix III.

A handwritten signature in black ink, reading "A. Bruce Steinwald". The signature is written in a cursive, flowing style.

A. Bruce Steinwald  
Director, Health Care—Economic  
and Payment Issues

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Ranking Minority Member  
Committee on Energy and Commerce  
House of Representatives

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# Appendix I: Scope and Methodology

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In conducting this study, we analyzed the Centers for Medicare & Medicaid Services (CMS) Facility Survey files, Medicare cost reports, and Medicare outpatient claims. We interviewed officials from CMS and the National Institute of Diabetes & Digestive & Kidney Diseases. We also interviewed representatives from the American Association of Kidney Patients, American Nephrology Nurses' Association, Forum of End Stage Renal Disease (ESRD) Networks, National Kidney Foundation, National Renal Administrators Association, and Renal Physicians Association; representatives from five national dialysis facility chains, a national manufacturer of dialysis equipment, and several private health insurance companies; and nephrologists who provide daily hemodialysis. We conducted site visits at three dialysis facilities, one of which provides daily hemodialysis, and interviewed officials at these facilities.

To analyze the supply of freestanding and hospital-based dialysis facilities, we used the Facility Survey files from 1998 through 2002, and to identify ESRD beneficiaries on dialysis, we used Medicare outpatient claims from 1998 through 2001, the most recent years for which data were available at the time of our analysis. From the Facility Survey files, we identified all dialysis facilities operating the entire year, opening during the year, and closing during the year, and the number of stations at each facility.<sup>1</sup> We identified a facility as offering a treatment method if it provided at least one treatment or had at least one patient using that method. From the Medicare outpatient claims, we identified Medicare ESRD beneficiaries receiving dialysis each year, and their residence by ZIP code. We then calculated the number of dialysis facilities operating the entire year and the number of beneficiaries receiving dialysis for each county in the 50 states and in the District of Columbia, which we considered a county. We determined the average number of facilities and stations in each county, weighted by the number of beneficiaries in each county. We defined a county as urban if it was in a metropolitan statistical area and as rural if it was outside a metropolitan statistical area, as determined by the Office of Management and Budget.<sup>2</sup> We assessed the reliability of the Facility Survey

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<sup>1</sup>Facilities indicate on their annual surveys whether they closed during the survey year. However, we found that many facilities that indicated they closed during the year then continued to operate in the next year. This discrepancy may occur for a variety of reasons, including when facilities indicate they are closing when they are actually changing ownership. We used the 2002 file to adjust the number of closings in 2001.

<sup>2</sup>For 1998 and 1999 analyses, we used metropolitan statistical area definitions as of June 30, 1996, and for 2000 and 2001 analyses, we used metropolitan statistical area definitions as of June 30, 1999.



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**Appendix I: Scope and Methodology**

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file and claims data by analyzing trends in the number of beneficiaries on dialysis and dialysis facilities over time and comparing these to trends reported by CMS. We determined that the data were reliable for our purposes.

To calculate payment-to-cost ratios for composite rate services only, we used cost reports for freestanding renal dialysis facilities from 1998 through 2001, the most recent data available. The Medicare payment methodology is the same for freestanding and hospital-based dialysis facilities, but we did not analyze cost reports or claims for hospital-based facilities because their reported costs are affected by decisions in allocating costs between the hospital and the dialysis facility. In 2001, about 84 percent of all dialysis facilities nationwide were freestanding. We first edited the cost reports to exclude those facilities located outside the 50 states or the District of Columbia, those with cost reporting periods less than 300 days, and those that reported composite rates outside the range of possible rates from the Medicare program. We excluded 577 of the 2,983 cost reports, or about 19 percent. From the remaining cost reports, we calculated each provider's total Medicare payments and total reported costs. We calculated the proportion of total cost attributable to Medicare beneficiaries using the proportion of each facility's treatments that was furnished to Medicare beneficiaries. We summed payments and costs across all providers to obtain payment-to-cost ratios from 1998 through 2001 weighted by total Medicare payments received by each facility. Additionally, we stratified ratios by dialysis treatment method, as reported in the cost reports. We assessed the reliability of the cost report data by comparing our payment-to-cost ratios to those published by the Medicare Payment Advisory Commission. We determined that the data were reliable for our purposes.

In order to calculate 2001 payment-to-cost ratios for overall costs, that is, composite rate services and separately billed drugs, we used 2001 cost reports for freestanding renal dialysis facilities and 2000 and 2001 Medicare outpatient claims data.<sup>3</sup> We first edited the cost reports to exclude those facilities located outside the 50 states or the District of Columbia, those with cost reporting periods fewer than 300 days, and those that reported composite rates outside the range of possible rates

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<sup>3</sup>We did not include separately billed laboratory services in our payment-to-cost ratios because they are billed by the laboratory that performed the test, rather than by the dialysis facility.

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**Appendix I: Scope and Methodology**

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from the Medicare program. Payment information for individual drugs is not available on Medicare outpatient claims prior to July 1, 2000, and therefore we did not calculate these ratios for years prior to 2001.<sup>4</sup> We used the claims data to obtain payments for separately billed drugs, as they are not available in the cost reports. We obtained the total costs of separately billed drugs from the cost reports and calculated the proportion attributable to Medicare beneficiaries using the proportion of each facility's treatments that was furnished to Medicare beneficiaries. We then added our previously calculated composite rate payments and costs and summed total payments and total costs for all providers to obtain an overall payment-to-cost ratio for 2001 weighted by total Medicare payments received by each facility. We stratified the ratios by size. We defined the size of the facility based on the 25th and 75th percentiles of total dialysis treatments each facility reported in its cost report. Small facilities are those reporting a number of dialysis treatments less than the 25th percentile, medium facilities are those reporting a number of dialysis treatments greater than or equal to the 25th percentile and less than or equal to the 75th percentile, and large facilities are those reporting a number of treatments greater than the 75th percentile. We could not calculate these ratios by treatment method, as separately billed drug costs are not reported by treatment method on the cost report.

In order to identify separately billed items or services frequently billed in association with in-facility hemodialysis, we used 2001 Medicare outpatient claims data. We limited our claims population to those that reported only in-facility hemodialysis and no other treatment method. We defined "frequently billed" as those separately billed services that were billed over 100,000 times annually. We excluded laboratory services because these are typically billed directly to Medicare by the laboratory, not by the dialysis facility. Medicare instructs providers to record each drug administration on the claim separately, and accordingly, we defined one administration of a drug as one record on the claim. It is possible, however, that some providers aggregate the units of several administrations. To the extent this is the case, the billing frequencies for these specific drugs likely underestimate the actual administration frequencies.

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<sup>4</sup>Prior to July 1, 2000, Medicare outpatient claim files provide the total payment for all services that a provider records on each claim, but not the individual payments for each service.

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**Appendix I: Scope and Methodology**

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To review cost and clinical data on daily hemodialysis, we examined 25 articles obtained through a MEDLINE literature search for studies on daily hemodialysis published from 1998 through 2002. We examined an additional 11 articles referred to us during our interviews.

We conducted our work from July 2002 through June 2004 in accordance with generally accepted government auditing standards.

## Appendix II: Comments from the Centers for Medicare & Medicaid Services




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator  
Washington, DC 20201

**DATE:** APR 27 2004

**TO:** A. Bruce Steinwald  
Director, Health Care-Economic  
and Payment Issues  
General Accounting Office

**FROM:** Mark B. McClellan, M.D., Ph.D.   
Administrator  
Centers for Medicare & Medicaid Services

**SUBJECT:** General Accounting Office Draft Report, *Medicare Dialysis Facilities: Beneficiary Access Stable, but Methodology Needs Improvement* (GAO-04-450)

Thank you for the opportunity to review the GAO draft report entitled *Medicare Dialysis Facilities: Beneficiary Access Stable, but Methodology Needs Improvement* (GAO 04-450), in which GAO recommended that the Centers for Medicare & Medicaid Services (CMS) first, redesign the prospective payment system (PPS) for dialysis facilities to bundle the costs of services delivered to Medicare beneficiaries into one payment amount. And that, second, this payment system should be based on facilities' allowable costs of delivering services.

The GAO posed two issues for analysis: (1) Given that the composite payment rates have only been minimally revised since their inception in 1983, has beneficiary access to outpatient maintenance dialysis been adversely affected? And (2) does the end stage renal disease (ESRD) composite rate payment system need to be revised to include separately billable services?

The GAO concluded that despite minimal changes to the ESRD composite payment rates, beneficiary access to dialysis services has not been impaired. Composite rate payments to dialysis facilities are less than composite rate costs. However, payments for separately billable dialysis services exceed separately billable costs by an amount more than sufficient to make up the shortfall and generally provide an overall profit margin. This unintended cross subsidization between composite rate and separately billable dialysis services should be eliminated by bundling all outpatient dialysis services into a single prospective payment amount based on ESRD facility costs.

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**Appendix II: Comments from the Centers for  
Medicare & Medicaid Services**

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The GAO's findings with respect to beneficiary access are similar to those of MEDPAC in a Report to Congress. While these findings are reassuring, we are concerned that GAO's analysis did not specifically address regional access issues of which we have been made aware, such as those in New England and New York. Regional office staff have informed us that hospitals are having difficulty discharging and placing ESRD patients in dialysis facilities in those areas.

We concur with the GAO's conclusion that all outpatient dialysis services should be bundled into a single prospective payment amount based on facility costs to the extent feasible. However, we point out that CMS currently does not have the statutory authority to implement this recommendation. As part of outpatient ESRD reform, section 623(d) of Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the development of a basic case mix adjustment to the composite payment rates, effective January 1, 2005. While the initial case mix adjustment will be restricted to comply with the MMA's directive that it reflect a "limited number of patient characteristics," adoption of such a risk adjuster will begin to address a major limitation of the current payment system, which is its inability to account for patient variation in resource consumption. The statute, however, specifically prohibits CMS from bundling any additional items and services into the composite payment rate.

Section 623(f) of the MMA requires the Secretary to submit a Report to Congress by October 1, 2005 detailing the design and features of a fully bundled ESRD PPS. The proposed fully bundled ESRD PPS will be the subject of a three-year demonstration project beginning January 1, 2006. Given the GAO's endorsement of a bundled ESRD PPS, we believe that its recommendation should be revised to acknowledge the statutory limitations to revising the payment system for dialysis services. It should also recognize CMS' sponsored research to develop the bundled payment system that has been underway since October 2000.

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## Appendix III: GAO Contact and Staff Acknowledgments

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### GAO Contact

Nancy A. Edwards, (202) 512-3340

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### Acknowledgments

Kevin J. Dietz, Joanna L. Hiatt, Maria Martino, and Yorick F. Uzes made major contributions to this report.

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